The Use of Pharmacoeoconomics and Pharmacoepidemiology in Your Local MTF P&T Process

by
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Presentation Objectives

- **Participants will be able to briefly discuss epidemiological factors that may influence decisions at the local P&T Committee.**
- **Participants will be able to describe some of the interaction(s) between epidemiology and pharmacoeconomics.**

Presentation Objectives

- **Participants will be able to describe what pharmacoepidemiology is and what it may potentially do you your P&T Committee.**

Pharmacoepidemiology

- **“Studies find overdose of redundant research”**

-Austin American Statesman, 8 Jan 06

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- 64 studies (randomized, controlled trials) of aprotinin.
- Almost all showed – patients who received aprotinin during surgery bled less.

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- All of this is leading some experts to ask a new question:

- “What part of “yes” don’t doctors understand?”

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- Testing in sub-groups ….
- Testing in varied doses, timing ….

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- Would the same be said of retrospective, database studies?
- The type of pharmacoepidemiology studies we are seeing more frequently.

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- They are not randomized, placebo controlled trials …
- Do we need a different standard?
- How much/many would do?

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Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Gordon C S Smith, Jill P Pell

Abstract

Objectives To determine whether parachutes are effective in preventing major trauma related to gravitational challenge.
Design Systematic review of randomised controlled trials.
Data sources: Medline, Web of Science, Embase, and the Cochrane Library databases; appropriate internet sites and citation lists.
Study selection: Studies showing the effects of using a parachute during free fall.
Main outcome measure Death or major trauma, defined as an injury severity score > 15.
Results We were unable to identify any randomised controlled trials of parachute intervention.
Conclusions As with many interventions intended to prevent ill health, the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomised controlled trials. Advocates of evidence based medicine have criticised the adoption of interventions evaluated by using only observational data. We think that everyone might benefit if the most radical protagonists of evidence based medicine organised and participated in a double blind, randomised, placebo controlled, crossover trial of the parachute.

Introduction

The parachute is used in recreational, voluntary sector, and military settings to reduce the risk of orthopaedic, head, and soft tissue injury after gravitational challenge, typically in the context of jumping from an aircraft. The perception that parachutes are a successful intervention is based largely on anecdotal evidence. Observational data have shown that their use is associated with morbidity and mortality, due to both failure of the intervention[1 2] and iatrogenic complications.[3] In addition, "natural history" studies of free fall indicate that failure to take or deploy a parachute does not inevitably result in an adverse outcome.[4] We therefore undertook a systematic review of randomised controlled trials of parachutes.

Methods

Literature search
We conducted the review in accordance with the QUOROM (quality of reporting of meta-analyses) guidelines.[5] We searched for randomised controlled trials of parachute use on Medline, Web of Science, Embase, the Cochrane Library, appropriate internet sites, and citation lists. Search words employed were "parachute" and "trial." We imposed no language restriction and included any studies that entailed jumping from a height greater than 100 metres. The accepted intervention was a fabric device, secured by strings to a harness worn by the participant and released (either automatically or manually) during free fall with the purpose of limiting the rate of descent. We excluded studies that had no control group.

Definition of outcomes
The major outcomes studied were death or major trauma, defined as an injury severity score greater than 15.[6]

Meta-analysis
Our statistical apprach was to assess outcomes in parachute and control groups by odds ratios and quantified the precision of estimates by 95% confidence intervals. We chose the Mantel-Haenszel test to assess heterogeneity, and sensitivity and subgroup analyses and fixed effects weighted regression techniques to explore causes of heterogeneity. We selected a funnel plot to assess publication bias visually and Egger's and Begg's tests to test it quantitatively. Stata software, version 7.0, was the tool for all statistical analyses.

Results

Our search strategy did not find any randomised controlled trials of the parachute.

Discussion

Evidence based pride and observational prejudice
It is a truth universally acknowledged that a medical intervention justified by observational data must be in want of verification through a randomised controlled

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Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials

Pharmacoepidemiology

- pharmaco **- drug or medicine**
- epidemiology **- study of the distribution and determination of diseases in population**
- pharmacoepidemiology **- the study of the use and effects of pharmaceutical products in populations**

Pharmacoepidemiology

- … is the study of the use and effects of drugs in large numbers of people
- …it is an applied field bridging clinical pharmacology and epidemiology

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- … is the application of epidemiological knowledge, and methods to the study of the effects - beneficial and adverse - of drug products in human populations

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- … it's who your patients are
- … it's how your patients respond to treatment
- … they define 'what it will cost you' to provide them with (good) health care

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- **Purpose of pharmacoepidemiologic studies (may include):**

  To provide useful information on the beneficial and harmful effects of drugs.

  To provide information in the assessment of risk to benefit ratios for the therapy for a particular patient

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- **Purpose of pharmacoepidemiologic studies:**

  What effect does managed care have on drug use?

  What effect does drug use have on managed care?

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- **The Interface between Pharmacoepidemiology and Pharmacoeconomics in a Managed Care Pharmacy**

  - **J Managed Care Pharmacy 1996**
  - **Lon Larson & Darrel Bjornson**

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- For pharmacoepidemiology –
- … pharmacoeconomics is the bridge or interface that makes pharmacoepidemiology data economically relevant.

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- For pharmacoeconomics specialists–
- … who are concerned with comparing costs and consequences - pharmacoepidemiology is the source of relevant data about the positive and negative consequences of drug therapies.

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- Different perspectives, different conclusions

	A	B	C	D	E	F
	Net “gain”/ patient	Costs/ patient	No. patients	Total Gain (AxC)	Total Cost (BxC)	Cost/Unit of Gain (E/D)
Drug 1	25 units	$500	40	1,000	$20,000	$20
Drug 2	40 units	$1,000	20	800	$20,000	$25
Drug 3	50 units	$2,000	10	500	$20,000	$40
Drug 4	10 units	$300	67	670	$20,000	$30

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Patient perspective: individual benefit maximized

	A	B	C	D	E	F
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Drug 4	10 units	$300	67	670	$20,000	$30

Plan perspective: number of patients treated is maximized

	A	B	C	D	E	F
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Drug 1	25 units	$500	40	1,000	$20,000	$20
Drug 2	40 units	$1,000	20	800	$20,000	$25
Drug 3	50 units	$2,000	10	500	$20,000	$40
Drug 4	10 units	$300	67	670	$20,000	$30

Plan perspective: gain is maximized

	A	B	C	D	E	F
	Net “gain”/ patient	Costs/ patient	No. patients	Total Gain (AxC)	Total Cost (BxC)	Cost/Unit of Gain (E/D)
Drug 1	25 units	$500	40	1,000	$20,000	$20
Drug 2	40 units	$1,000	20	800	$20,000	$25
Drug 3	50 units	$2,000	10	500	$20,000	$40
Drug 4	10 units	$300	67	670	$20,000	$30

When resources are limited: the maximum gain is achieved by selecting alternatives in the order of their cost-

	A	B	C	D	E	F
	Net “gain”/ patient	Costs/ patient	No. patients	Total Gain (AxC)	Total Cost (BxC)	Cost/Unit of Gain (E/D)
Drug 5	30 units	$1,000	40	1,200	$40,000	$33
Drug 6	15 units	$300	40	600	$12,000	$20
Difference	15	$700		600	$28,000	$47

Drug 5 is a new drug (more effective, more costly). Drug 6 is on the formulary. Is it worth it?

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- Key points –
- Health care from the perspective of the individual patient and from that of the population can lead to conflicting priorities.

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- **Key points –**
- **Adopting a population perspective is a major change for health professionals who have been conditioned to view the health of a population one patient at a time.**

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- Key points –
- Managed care organizations have the goal of maximally improving the health of their membership and not only individual members.

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- Key points –
- Further, they have limited resources to accomplish this goal.
- In such a situation, analyses of costs and effectiveness can assist decision makers as they allocate resources.

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- **Geoffrey Rose's Big Idea**
- **Changing the population distribution of a risk factor is better than targeting people at high risk.**

- or

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- Rose's rationale for prevention –

- "It is better to be healthy than ill or dead."

- or

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- **The prevention paradox -**

- **“Preventive actions that greatly benefit the population at large may bring only small benefits for individual patients.”**

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- Your decisions –

- You can please all of the people, some of the time
- You can please some of the people, all of the time

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- Your decisions –
- But you can’t please all of the people, all of the time …

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- Your decisions –
- Unless you have unlimited resources

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Coffee could reduce breast cancer risk: report

- Women with gene mutations that carry a high risk of developing breast cancer could decrease their risk by drinking a lot of coffee, a Canadian research team has found.
- University of Toronto researcher Dr Steven A Narod and his team examined the links between coffee consumption and the risk of breast cancer among 1,690 high-risk women with BRCA1 or BRCA2 mutations.
- They found the likelihood of developing breast cancer among BRCA mutation carriers who drank one to three cups of coffee daily was reduced by 10 per cent, compared to those who did not drink coffee.
- The risk dropped by 25 per cent for those who drank four to five cups and 69 per cent for women who drank six or more cups of coffee.
- The report, published in the *International Journal of Cancer*, says the team found significant protection from coffee for women with a BRCA1 mutation but not for carriers of a BRCA2 mutation.
- The investigators noted that coffee is an important source of phytoestrogens, which may have protective effects.
- The study included women from 40 clinical centres in four countries.
- A self-administered questionnaire was used to assess the average lifetime coffee consumption.
- - Reuters © 2006 Australian Broadcasting Corporation

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- Some decisions are made at the local level—the hospital, health plan or practitioner practice level. For example, treatment guidelines and formulary decisions can be at the local level. Please note that in the U.S. most decisions are done at the local level, however with the advent of major health care programs this is changing. More and more decisions are being made at higher levels.
- The applications of economic analyses are at the both the “central” and “local” area.

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- **Who the patients are – their peculiarities, differences (what they look-like) – must be considered at both the local and national levels when decisions are being made.**

Thanks so much. It has been a pleasure.

Enjoy the meeting!

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